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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/702,303	11/06/2003	Arnold R. Leiboff	461.1008	8007

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EXAMINER

HALL, DEANNA K

ART UNIT	PAPER NUMBER
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3767

MAIL DATE	DELIVERY MODE
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08/24/2007

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/702,303

Applicant(s)

LEIBOFF, ARNOLD R.

Examiner

Deanna K. Hall

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 06 November 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-28 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-28 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 06 November 2003 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date See Continuation Sheet.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____.

Continuation of Attachment(s) 3). Information Disclosure Statement(s) (PTO/SB/08), Paper No(s)/Mail Date :November 6, 2003; April 27, 2006; February 1, 2007.

DETAILED ACTION

Information Disclosure Statement

1. The information disclosure statements (IDS) submitted on November 6, 2003, April 27, 2006 and February 1, 2007 are in compliance with the provisions of 37 CFR 1.97(b). Accordingly, the IDSs are being considered by the Examiner.

Claim Rejections - 35 USC § 102

2. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

3. **Claims 1-2, 4-7, 9-11, 14-17, 19-24 and 26-28 are rejected under 35 U.S.C. 102(b) as being anticipated by Stevens (US 4,811,743).**

Stevens discloses an elongate, resilient shaft 20 with a spherical bulbous enlargement 22 having a smooth, arcuate outer surface arranged at the distal end, See Fig. 2. Stevens teaches passing the shaft 20 having the bulbous enlargement 22 into a body cavity and sliding an irrigating tube (catheter) over or along the guidewire C1 L55-58, C3 L10-13 to direct fluid through the irrigating tube C2 L12-15.

Stevens further discloses that the portion of the shaft attached to the bulbous enlargement is more flexible than the remainder of the shaft C3 L9-10; a tapered shaft, C3 L63-64, Fig. 4; and a shaft comprising a central metal wire 24 surrounded by a coil 26, Fig. 2.

Since the outside diameter of the shaft 26 and bulbous enlargement 22 is chosen to fit within the catheter (irrigating tube) to be positioned within the guidewire C3 L32-34, the guidewire 20 of Stevens will be able to be withdrawn after catheter placement. Further, Stevens provides this smooth bulbous enlargement so as to not perforate or damage the wall of the body cavity during guiding or insertion C1 L23-25. The guidewire is guided through the body cavity by manipulating the bulbous enlargement C1 L48-58.

Claim Rejections - 35 USC § 103

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

5. **Claims 3, 13, 18 and 25 are rejected under 35 U.S.C. 103(a) as being unpatentable over Stevens (US 4,811,743).**

Stevens discloses the invention as substantially claimed (see above). However, Stevens fails to disclose the specific diameter range of the bulbous enlargement 22 of about 0.25 inches to about 0.75 inches. It would have been obvious to one having ordinary skill in the art at the time the invention was made to increase the outside

diameter of the shaft and bulbous enlargement to fit within the catheter to be positioned with the guidewire, See C2 L64-65, C3 L32-34 and C4 L19-21. Such a modification would have involved a mere change in the size of a component and a change in size is generally recognized as being within the level of ordinary skill in the art. *In re Rose*, 105 USPQ 237 (CCPA 1955).

6. Claims 8 and 12 are rejected under 35 U.S.C. 103(a) as being unpatentable over Stevens ('743) in view of Majlessi (4,842,583).

Stevens discloses the invention as substantially claimed (see above). Although the catheter guidewire of Stevens is disclosed for use in inserting a catheter into a subject for patient examination or treatment, See abstract and C2 L12-15, Stevens does not directly disclose that the body cavity is the colon and the guidewire is pushed through the anal sphincter and rectum into the colon. Majlessi, in the analogous art, teaches a flexible colonic irrigation tube 10 for insertion into the colon through the rectal opening 30, C4 L20-22. Therefore it would have been obvious to a person having ordinary skill in the art at the time of the invention to modify the device of Stevens with the flexible colonic irrigation tube as taught by Majlessi for guiding a tube (catheter) to the colon to be irrigated. Further, Majlessi teaches grasping the bulbous enlargement and pulling the guidewire outward from the body cavity to compress and shorten the distance between an entrance to the body cavity and a treatment site C3 L54-61.

With reference to claim 13, the combination of Stevens/Majlessi teaches the claimed invention except for the specific diameter range of the bulbous enlargement 22 of about 0.25 inches to about 0.75 inches. It would have been obvious to one having

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ordinary skill in the art at the time the invention was made to increase the outside diameter of the shaft and bulbous enlargement to fit within the catheter to be positioned with the guidewire, See C2 L64-65, C3 L32-34 and C4 L19-21. Such a modification would have involved a mere change in the size of a component and a change in size is generally recognized as being within the level of ordinary skill in the art. *In re Rose*, 105 USPQ 237 (CCPA 1955).

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Deanna K. Hall whose telephone number is 571-272-2819. The examiner can normally be reached on M-F 8:00am-4:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, LoAn Thanh can be reached on 571-272-4966. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Deanna K. Hall
Examiner
AU 3767

dkh



LOAN H. THANH
PRIMARY EXAMINER